

July 12, 2001

Dr. James Reisa  
Director  
Board of Environmental Studies and Toxicology  
Division on Earth and Life Studies  
National Research Council of the  
National Academy of Sciences  
2101 Constitution Avenue, N.W.  
Washington, DC 20418

**Subject: NRC Scientific Integrity Procedures and the Arsenic Update Subcommittee**

Dear Dr. Reisa:

We are writing once again about the National Research Council's apparent difficulty in conducting an impartial inquiry into the risks of arsenic in drinking water, as requested by the Environmental Protection Agency. As we discussed earlier, I was pleased that Dr. Goyer, the arsenic subcommittee chair, asked the subcommittee to make the required disclosures regarding background and public positions, under the NRC section 15 Federal Advisory Committee Act procedures, at the second public data meeting on June 20. This was one of the major requests made in the June 19<sup>th</sup> letter from Susan Walthall, the Acting Chief Counsel for Advocacy, in order to help assure the scientific integrity of the NRC panel process. However, as we discussed soon after that meeting, we continue to be concerned with the apparent lack of balance of the current panel members.

Despite the considerable controversy about the apparent lack of balance among the panelists (see June 19<sup>th</sup> Advocacy letter and my May 21<sup>st</sup> testimony), I was quite surprised to hear the one-sided presentation on risks of arsenic in drinking water by two panelists before EPA Administrator Whitman at the June 20<sup>th</sup> meeting. I describe that briefing below:

(1) Both Drs. Cantor and Eaton stressed how close the arsenic levels in certain epidemiological studies were to the current 50 ppb standard, unlike studies of other chemicals, implying that the projected arsenic risks were unusually reliable. However, both failed to mention any possibility of the existence of a threshold or sublinearity, which would lower the risk. There is now a significant and growing body of research that indicates that there is no increased risk of bladder or skin cancer with arsenic exposures below at least 100 ppb (inorganic and organic forms of arsenic) in drinking water, which I presume the subcommittee is now reviewing. Even the 1999 panel report specifically stated that the only plausible arsenic mechanisms did involve nonlinearity.

(2) Although the Taiwan, Argentina and Chile studies were mentioned by the speakers (all studies showing cancer effects), there was no disclosure of the many factors that would cause the risks in these countries to be considerably higher than in the U.S.: selenium levels, nutritional status, health status, smoking status, and diet. Indeed, sublinearity and the population-related factors are among the key issues that are specifically part of the charge to the NRC.

(3) Even more amazingly, no mention was made of the Utah study, the only large scale study of arsenic exposure in the U.S., where the EPA Science Advisory Board found “no evidence of either bladder or lung cancer where mean drinking water concentrations approached 200 ppb. While these concentrations are up to an order of magnitude lower than found in sites where positive associations with cancer have been obtained, these results give rise to significant questions about whether the Taiwan data apply quantitatively to those U.S. populations that have a more adequate nutritional status.” EPA SAB Report at 30. Thus, there is no direct evidence that U.S. citizens would experience any excess bladder or lung cancers due to arsenic exposure at the concentrations found in the U.S.

I was equally concerned with the additional remarks by the subcommittee chair, Dr. Goyer. Dr. Goyer was also the chairman of the subcommittee that authored the 1999 study, which I criticized specifically in my May testimony before the subcommittee.

(1) In Dr. Goyer’s discussion of the NRC charge, he made no mention of the “clarifications” contained in the April 23, 2001 letter from Acting EPA Assistant Administrator for Water, Diane Regas, which direct attention to several factors omitted in the earlier April 6th NRC letter that might lead toward a less stringent standard, including no reference to a review of the EPA Science Advisory Board report conclusions, and no mention of a review of the conclusions on the latency period between the exposure to arsenic in drinking water and increased incidence of cancer based on existing research.

(2) As you know, the May 16<sup>th</sup> letter from Susan Walthall, Acting Chief Counsel for Advocacy, expressed concern about the NRC’s apparent violation of its 1992 bias policy by including five members of the 1999 panel in the new panel of eight members who will be reviewing their own work in the 1999 report. Dr. Goyer’s remarks indicating that the panel will be “updating,” but not reviewing the previous panel’s work was puzzling. The five returning NRC subcommittee members must be reviewing their earlier work because the EPA charge includes a review of the basis of EPA’s 2000 risk assessment, which in turn relies on the 1999 NRC report, as I explain below.

The April 2001 NRC charges include a review of whether the Southwestern Taiwanese studies “remain the best data for dose response and risk estimation.” In addition, the charge includes the following requirement, “[d]etermine if EPA’s risk estimates at 3, 5, 10, and 20 .g/L are consistent with available scientific information, including information from new studies.” In other words, the NRC must review both the EPA risk estimation methodology and the Taiwanese data. That almost identical

methodology and that use of the Southwestern Taiwanese data were the basis for the 1999 NRC "sample" risk "assessment" performed by Dr. Louise Ryan, who also serves on the current panel. Any evaluation of the EPA risk assessment necessarily requires a review of the 1999 report methodology and data.

Will the subcommittee avoid assessing the EPA methodology and the Taiwanese data? Frankly, I believe that the panel must do both assessments to meet its charge. If the subcommittee were simply reviewing new references, I would agree with Dr. Goyer's description. However, EPA asked the committee to review the agency assessment, which cannot be separated from the NRC work, because EPA did little more than slightly adjust the methodology (interestingly enough, despite the very clear and explicit NRC instructions not to do so alone).

Considering the fact that these one-sided statements were made in a public session with interested parties watching, I am even more concerned about what may transpire behind NRC's closed doors. I hope my concern is misplaced. I respectfully suggest that the NRC staff redouble its efforts to assure the integrity of the process. I trust these comments will prove useful to the subcommittee. If you have any questions or comments, I can be reached at 202-205-6964 (fax 205-6928; e-mail [kevin.bromberg@sba.gov](mailto:kevin.bromberg@sba.gov)).

Sincerely,

Kevin Bromberg  
Assistant Chief Counsel  
for Environmental Policy

cc: Administrator Whitman, EPA  
Tom Gibson, EPA  
Diane Regas, EPA  
Don Arbuckle, OMB